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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,539	10/04/1999	LOUIS S. KUCERA	0044317U3	9782
28977	7590	03/01/2006	EXAMINER	
MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/412,539

Applicant(s)

KUCERA ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 56,69,71,107,110 and 112-130 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56,69,71,107,110 and 112-130 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 56, 69, 71, 107, 110 and 112-130 are pending in the application.

This action is in response to applicants' amendment filed December 22, 2005.

Claims 56, 69, 71, 107, 110 and 112 have been amended, claims 70 and 111 have been canceled and claims 113-130 are newly added

### ***Response to Amendment***

Applicants' arguments filed December 22, 2005 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 56, 69-71, 107 and 110-112 as being obvious over WO 91/19726 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive. The applicant's stated that the proper inquiry for obviousness is whether the references suggest the invention and provide one of ordinary skill in the art with a reasonable expectation of success and that the fact that a claimed species or subgenus is encompassed by a prior art genus is insufficient by itself to establish a *prima facie* case of obviousness. The applicants further calculated that the number of possible choices for each of the variables would yield over 2.1 million possibilities for ether lipid-nucleosides according to Formula I. However, using the applicants calculating method of the number of possible ether lipid nucleosides the number of possible compounds is only 400 ( $10 \times 20 \times 2 \times 1 \times 1 \times 1 \times 1 \times 1 \times 1 \times 1$ ) rather than the 2,112,00 urged by the applicant, which is in view of the preferred embodiments set forth by the dependent claims 4, 5, 7 and 12 which states:

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Claim 4 is such that **W<sub>1</sub> is NHC(=O)**;  
Claim 5 is such that **W<sub>2</sub> is O**;  
Claim 7 is such that **Y is N<sub>3</sub>; Z is H; and B is thymine**;  
Claim 12 is such that **n is zero; X<sub>1</sub> is O; and X<sub>2</sub> is O**;

specifically defines the variables defined herein. The specification of WO 91/19726

teaches a preferred embodiment of formula (I) where W<sub>1</sub> is S, O, NHC(=O) or NH.

**Preferably W<sub>1</sub> is NHC(=O).** W<sub>2</sub> is S, O, NHC(=O), OC(=O), NH or a covalent bond.

**Preferably W<sub>2</sub> is O.** n is zero or one. X<sub>1</sub> and X<sub>2</sub> are each independently oxygen or a covalent bond, subject to the proviso that **when n is zero, then at least either X<sub>1</sub> or X<sub>2</sub> is O.** Y is H, F or N<sub>3</sub>; Z is H or F; or Y and Z together are a covalent bond (i.e., form a didehydro). Preferably, Y is H or N<sub>3</sub>; Z is H; or Y and Z together are a covalent bond.

**More preferably, Y is H or N<sub>3</sub> and Z is H.** (at lines 1-13 on page 3). Thus one of ordinary skill in the art would be motivated to select a compound where **W<sub>1</sub> is NHC(=O)** or O; **W<sub>2</sub> is O, Y is N<sub>3</sub>, Z is H, B is thymine; n is zero, X<sub>1</sub> is O and X<sub>2</sub> is O** from the preferred embodiments of WO 91/19726.

Claims 56, 69, 71, 107, 110, 112 and newly added claims 113-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piantadosi et al., WO 91/19726, for reasons of record and stated above.

2. With regards to the obviousness-type double patenting rejection as being unpatentable over the claims of U.S. Patent No. 6,030,960 in the last office action, the applicants stated that a terminal disclaimer had been filed and thus renders moot the obviousness-type double patenting rejection over U.S. Patent No. 6,030,960. However, a terminal disclaimer for U.S. Patent No. 6,030,960 was not received.

Claims 56, 69, 71, 107, 110, 112 and newly added claims 113-130 are rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over the claims of U.S. Patent No. 6,030,960, for reasons of record and stated above.

In view of the amendment dated December 22, 2005, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 120, 121, 129 and 130 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The addition of claims 120, 121, 129 and 130, which includes dosages is not described in the specification with respect to two species claimed herein.

Applicant is required to cancel the new matter in the reply to this Office action.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Brenda Coleman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Brenda L. Coleman  
Primary Examiner Art Unit 1624  
February 24, 2006